IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PSA, LLC, et al.	:	CIVIL ACTION
v.	:	
ALBERTO R. GONZALES, et al.	:	NO. 06-3212

MEMORANDUM

Dalzell, J. November 13, 2006

Plaintiffs in this action seek both a declaratory judgment that their proposed Internet pharmacy operation is lawful and an injunction preventing the Department of Justice (DOJ) and the Drug Enforcement Agency (DEA) from prosecuting them. The Government moves to dismiss under Fed. R. Civ. P. 12(b)(1), arguing that (1) plaintiffs lack standing, (2) the matter is not ripe for adjudication, and (3) 21 U.S.C. § 877 vests exclusive jurisdiction over this matter in the courts of appeals.

Although we find that Section 877 does not bar our jurisdiction, but because we agree that plaintiffs lack standing and that their claims are not ripe for adjudication, we will grant defendants' motion and dismiss.

Standard of Review

In resolving a motion to dismiss for failure to state a claim, we must, of course, "accept as true all allegations in the complaint and all reasonable inferences that can be drawn from them after construing them in the light most favorable to the non-movant." Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250 (3d Cir. 1994). Here, however, we deal with a motion to dismiss for lack of subject matter jurisdiction, which

presents a much different context. Because defendants claim that no subject matter jurisdiction exists, "the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." Mortensen v. First Fed. Sav. and Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977). In addition, plaintiffs bear the burden of pleading facts adequate to support subject matter jurisdiction. Id. Though we will accept as true the facts as plaintiffs have alleged them,[1] we will not be so generous with our inferences from those facts as we would be on a motion under Rule 12(b)(6). Further, where defendants credibly assert that plaintiffs' allegations are false or misleading, we may weigh that evidence and reach a preliminary conclusion as to the truth.

Factual Background

Plaintiff PSA, LLC proposes to act[2] as an Internet intermediary between doctors and registered pharmacists with the intention of allowing the writing and filling of prescriptions

[1] Plaintiffs have, after all, not had much opportunity to discover or offer evidence in support of their interpretation of the facts.

[2] At one point in the complaint, plaintiffs state that "PSA and Napoli have acted as Internet intermediaries." Am. Compl. ¶ 3 (emphasis added). Throughout the rest of the complaint, however, it appears that plaintiffs are seeking only to act as intermediaries in the future. This lack of clarity may be driven by a desire on the part of plaintiffs not to admit that they have violated federal law. Given the nature of their challenge, however, it is vital that such past violations, if they have occurred, be alleged plainly. Because the complaint does not address the nature of their past actions, we will proceed under the assumption that plaintiffs have not yet committed violations of the challenged regulations.

for pharmaceuticals over the Internet. Plaintiff Christopher Napoli is one of PSA's principals. Plaintiff Joseph J. Carozza is a physician, licensed to practice in New York state, and plaintiff Alan J. Winter[3] is a registered pharmacist who operates a pharmacy in Ogden, Utah. Both plan to work with PSA to write and fill prescriptions over the Internet.

Plaintiffs propose a business model in which patients make written requests for prescription medications through PSA.[4] Those requests, which would include medical history and other supporting information, will be forwarded to a physician for review. If necessary, the physician may contact the patient by telephone to discuss the request. PSA will compensate doctors based on a negotiated fee for each request reviewed. If the doctor determines that the medication is warranted, he or she will write a prescription for the patient. That prescription will be filled by one of the associated pharmacies and delivered to the patient by mail.[5] Although PSA will not act as an intermediary for Schedule II drugs or for Schedule III narcotics,

---

[3] The original complaint identified one of the plaintiffs as Alan White. Either Mr. Winter and Mr. White are the same person or Mr. Winter has been substituted as a plaintiff.

[4] The exact nature of the written requests is not clear, but we assume they could be obtained either through an interactive Web site or via email.

[5] The complaint lays out a number of safeguards inherent in the business plan, including declining to prescribe certain controlled substances. Although these safeguards might affect a future determination as to whether this activity is lawful, they do not affect our determination as to whether there is currently a live case or controversy.

it will dispense some controlled substances. "Should the Court deem it necessary to comply with applicable law," PSA would also employ nurses or nurse practitioners to conduct physical examinations of patients prior to review of the physicians' requests. Am. Compl. ¶ 15(G).

Federal regulations require that a prescription for a controlled substance[6] "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Acting in the usual course of professional practice requires a bona fide relationship between the doctor and the patient. See Dispensing and Purchasing Controlled Substances over the Internet, 66 Fed. Reg. 21181, 21182 (Apr. 27, 2001). The DEA has described it as "unlikely" that such a relationship could be formed purely by contact over the Internet. Id. at 21183.

Plaintiffs allege that the Department of Justice is informing credit card processors that business models such as the one plaintiffs propose are unlawful. Some companies and individuals have been prosecuted for selling pharmaceuticals, particularly controlled substances, over the Internet, though it is not clear how closely the business models in those cases match PSA's proposed model. There is legislation currently pending in Congress, the "Ryan Haight Internet Pharmacy Consumer Protection Act of 2005," H.R. 840, that would ban essentially all sales of

[6] Not all medications for which a prescription is required are controlled substances. Controlled substances include certain drugs with a particularly high risk for dependency or abuse and are subject to additional restrictions.

prescription pharmaceuticals over the Internet that were not based on an in-person medical examination.

Plaintiffs seek a declaration from this Court that the DOJ and the DEA lack the authority to find that a legitimate medical relationship cannot exist without an in-person examination,[7] that defendants do not have authority to interfere with PSA's business model as described, and that the proposed business model does not constitute illegal trafficking in controlled substances. Plaintiffs also ask us to enjoin defendants from interfering with their financial and business relationships.

Analysis

Defendants raise three grounds for dismissal. They argue that plaintiffs lack standing, the claims are not ripe, and 21 U.S.C. § 877 vests jurisdiction of this matter exclusively in the courts of appeals.

Both the standing and ripeness doctrines arise out of the "case or controversy" requirement of article III, section 2 of the Constitution. The Supreme Court has interpreted this requirement as preventing the federal courts from offering advisory opinions in the absence of a full-blown controversy. See, e.g., Flast v. Cohen, 392 U.S. 83, 96-97 (1968). Even in cases seeking declaratory relief, the case or controversy requirement must be satisfied . Skelly Oil Co. v. Phillips

[7] They do not claim that Congress lacks the authority to make such a finding or that H.R. 840, if adopted, would be unconstitutional.

Petroleum Co., 339 U.S. 667, 671 (1950). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Maryland Cas. Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1940).

Of the many doctrines created to enforce the case or controversy requirement, the two at issue here are standing and ripeness. Standing concerns itself with who may properly bring an action; ripeness deals with when that action may be brought. See Armstrong World Indus. v. Adams, 961 F.2d 405, 411 n.13 (3d Cir. 1992).

A. Standing

Though some aspects of the standing inquiry are prudential and left to the sound discretion of the court, because of its basis in the case or controversy requirement, standing has a constitutional dimension as well. This is the "irreducible constitutional minimum" of the standing inquiry. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). "Constitutional standing has three elements, all of which must be met: (1) the plaintiff must have suffered an injury in fact; (2) there must be a causal nexus between that injury and the conduct complained of; and (3) it must be likely that the injury will be redressed by a favorable judicial decision." Joint Stock Soc'y v. UDV N. Am., Inc., 266 F.3d 164, 175 (3d Cir. 2001).

Though "an identifiable trifle" of harm is all that is required to demonstrate an injury in fact, United States v. Students Challenging Regulatory Agency Procedures, 412 U.S. 669, 689 n.14 (1973), that harm must be "an invasion of a legally protected interest" that is "concrete and particularized," Lujan, 504 U.S. at 560. Plaintiffs bear the burden of alleging facts that demonstrate that they have suffered such an injury. Renne v. Geary, 501 U.S. 312, 316 (1991). Vague and conclusory statements of injury do not suffice to carry this burden.

Plaintiffs claim that they meet this requirement because people doing "just what Plaintiffs are doing" have been indicted and arrested. It does not appear, however, that this is precisely true. In the only specific case[8] identified by either side as being analogous to this one, about 70% of the prescriptions the company processed were for hydrocodone, United States v. Fuchs, --- F.3d ----, 2006 WL 2949288 (5th Cir. Oct. 17, 2006) at *3, a drug that PSA will not prescribe, Am. Compl. ¶ 15(A). Since it appears that the enforcement activities that plaintiffs fear are focused on controlled substances rather than targeting prescription drugs in general, that distinction makes Fuchs of only passing relevance to the case here.

[8] Plaintiffs make reference to an eighty-five count indictment against certain individuals, Am. Compl. ¶ 22, but provide no information about the case. It is, therefore, impossible for us to consider that case and its similarity to the facts here. The fact that "individuals alleged to have engaged in electronic commerce in pharmaceuticals" have been indicted, id., is hardly sufficient to act as a basis for plaintiffs' fear of imminent prosecution.

While it is true that a "genuine threat of imminent prosecution," Thomas v. Anchorage Equal Rights Comm'n, 220 F.3d 1134, 1139 (9th Cir. 2000) (internal quotation omitted), often suffices to confer standing on those who face it, we cannot conclude on the record before us that such a threat hangs over plaintiffs. It is not apparent that plaintiffs' proposed business plan even violates the terms of the DEA regulations that plaintiffs challenge. The DEA notice cited above says merely that the formation of a proper doctor patient relationship entirely based on communication over the Internet is "unlikely." 66 Fed. Reg. 21181, 21183. The same notice makes clear that an in-person exam supervised by the physician but actually given by a nurse -- a step plaintiffs have stated they are willing to take -- would, if compliant with state law, suffice. Id. While the testimony of Joseph T. Rannazzisi before a House subcommittee does specifically say that "[a] legitimate doctor-patient relationship includes a face-to face [sic] consultation," Compl. Exh. A, at 3, the testimony of an Acting Deputy Assistant Administrator before a congressional subcommittee hardly constitutes a sufficiently conclusive statement of policy to serve as the predicate for a declaratory judgment action.

Plaintiffs make much of the fact that the DOJ is encouraging United States Attorneys to seek indictments against Internet pharmacies. Am. Compl. ¶ 21. While that is apparently the case, the United States Attorneys' Bulletin cited, see Charlotte J. Mapes, Internet Pharmacies and the Unlawful Distribution of Controlled Substances, U.S. Attorneys' Bull.,

Sept. 2005, at 43, takes no position on what business practices might constitute a violation of drug trafficking statutes. In particular, the bulletin takes no position on what level of interaction with a physician is required before dispensing drugs in the course of legitimate medical practice. Certainly, if Dr. Carrozza's participation in plaintiffs' business model is in violation of New York's medical licensing statutes, the DEA is entitled to investigate and the U.S. Attorney can seek an indictment for violation of the Controlled Substances Act. Plaintiffs' claim relies on the allegation that the DOJ and its subsidiary agencies have improperly defined legitimate medical practice. Since the cited bulletin does not refer to any particular definition of legitimate medical practice, and since it does not appear that anyone adopting a business model materially similar to plaintiffs' has been prosecuted, the bulletin does not bolster plaintiffs' claim that prosecution against them is looming.

Plaintiffs also allege injury due to defendants' disruption of their financial relationships with other companies. There are, however, no specific allegations regarding companies or methods of interference. This is exactly the sort of conclusory allegation that fails to carry plaintiffs' burden of demonstrating that they have suffered a particularized injury. The fact that the DOJ has told some financial institutions that some Internet pharmacies may be in violation of federal law does not show even the "identifiable trifle" of harm that is required. S.C.R.A.P., 412 U.S. at 689 n.14.

Because plaintiffs have failed to demonstrate an invasion of a "concrete and particularized" legally protected interest, Lujan, 504 U.S. at 560, they do not meet the constitutional requirements for standing.

B. Ripeness

The ripeness inquiry prevents federal courts from "entangling themselves in abstract disagreements." Abbott Labs. v. Gardner, 387 U.S. 136, 148 (1967), overruled on other grounds by Califano v. Sanders, 430 U.S. 99 (1977). The determination of ripeness turns on "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Id. at 149. For declaratory judgment actions, our Court of Appeals has adopted a ripeness inquiry that requires us to look at "(1) the adversity of the parties' interests, (2) the conclusiveness of the judgment, and (3) the utility of the judgment." Pic-a-State PA, Inc. v. Reno, 76 F.3d 1294, 1298 (3d Cir. 1996). We will examine each of these elements in turn.

1. Adversity of Interest

"For there to be an actual controversy the defendant must be so situated that the parties have adverse legal interests." Step-Saver Data Sys. v. Wyse Tech., 912 F.2d 643, 648 (3d Cir. 1990) (quoting 10A Charles A. Wright, et al., Federal Practice and Procedure § 2757 (2d ed. 1983)). Certainly, that requirement would be met in a case like Pic-a-State where the plaintiff had actually ceased operation of its profitable business in response to the passage of a new state law. "[W]here

a regulation requires immediate and significant change in the plaintiffs' conduct of their affairs," a declaratory judgment action is ripe for decision. Abbott Labs., 387 U.S. at 153.

Here it does not appear that plaintiffs have modified their activities out of concern that they will face prosecution. We hasten to add that we do not intend to imply that a change in conduct is a prerequisite for a declaratory judgment action. In its absence, however, plaintiffs must show by some other means that an actual adversity of interest is present. Here, by contrast, it appears that, before commencing a possibly unlawful activity, plaintiffs want a promise from the Court that they will not face prosecution. That is the sort of reassurance that private attorneys routinely provide in comfort letters; it is not what federal courts do in declaratory judgments.

The surest sign that a case lacks sufficient adversity to be ripe for decision is when the dispute between the parties is contingent on some future event. In Step-Saver, the plaintiff sought a declaration that, if other suits currently pending against it found that there were defects in the product, the defendant would be liable. The court found that, because the harm for which Step-Saver sought a remedy -- namely, a finding of liability against Step-Saver in the pending suits -- had not yet occurred, there was not an adversity of interest between the parties.

Here, because both the circumstances under which the DOJ will prosecute Internet pharmacies and the exact details of plaintiffs' business model are unclear, we have a similarly

contingent dispute. It appears, for example, that if plaintiffs were to have each patient examined by a nurse at the direction of the prescribing physician, they would be in conformity with the DEA's present guidelines for prescriptions. See 66 Fed. Reg. 21181, 21183. Similarly, it appears that the DEA has chosen to focus on pharmacies who primarily prescribe controlled substances, a group that probably does not include plaintiffs. See, e.g., Fuchs, 2006 WL 2949288.

Plaintiffs have, in fact, unwittingly identified the precise problem with their case when they promise that, "[s]hould the Court deem it necessary to comply with applicable law," PSA would employ nurses as contractors to examine patients. Am. Compl. ¶ 15(G). The Declaratory Judgment Act does not entitle entrepreneurs to ask a federal court "which of these business models is least likely to get me in in trouble" or "how can I modify my business to avoid prosecution." But that is precisely what plaintiffs ask in this suit.

2. Conclusiveness

We must next determine if the case stems from a "real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." Step-Saver, 912 F.2d at 649 (quoting Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 241 (1937)). This phase of the inquiry looks at whether the factual record is sufficiently developed that the dispute can now be resolved once and for all.

Our Court of Appeals has noted that where the question presented is a purely or predominantly legal one,[9] the need for a developed factual record is decidedly reduced. See Pic-a-State, 76 F.3d at 1300 (citing cases). In cases where a plaintiff's claim "is unlikely to change in substance or in clarity by virtue of an actual prosecution," pre-enforcement declaratory judgment actions have also been found to be conclusive. Armstrong, 961 F.2d at 421 (quoting Atlanta Gas Light Co. v. U.S. Dep't of Energy, 666 F.2d 1359, 1364 n.7 (11th Cir. 1982)).

This case presents neither of those situations. Plaintiffs here do not seek a declaration that some action of the DEA or the DOJ is per se illegal, but only that it is illegal as applied to their business model. That necessarily requires a high degree of factual clarity regarding that business model, a clarity notably lacking in the complaint.[10] Neither does plaintiffs' claim present a situation in which waiting for an actual or specifically threatened prosecution will leave their claim largely unchanged. Answers to the outstanding questions about both the DEA's focus on sales of controlled substances and the portion of PSA's business that controlled substances will constitute -- both of which would be clarified by an actual

[9] This situation would, of course, be most clearly presented in a facial challenge to the constitutionality of a statute or regulation.

[10] This does not appear to be merely a defect in the pleadings. As we understand the situation, the same lack of clarity we find in the complaint is present in plaintiffs' actual plans.

prosecution -- would significantly focus this proceeding.[11] An unequivocal statement as to whether PSA's model does or does not include the use of nurses to examine patients would also make any judgment we might issue more conclusive as to the parties.[12]

On the facts as they exist now, were we inclined to grant plaintiffs the declaratory judgment they seek, we would either need to define the scope of that judgment overly broadly in order to encompass likely future developments or face the possibility that, depending on those developments, our judgment would have no practical effect. It is the purpose of the ripeness requirement to avoid just this sort of inconclusive outcome.

3. Utility

The utility factor addresses the practical usefulness of the judgment the plaintiffs seek. The question we ask in determining utility is "whether the parties' plans of actions

---

[11] There is also, of course, the question of whether Congress will take any action to clarify the nature of the doctor-patient relationship in an electronic commerce setting. Given the rapid proliferation of Internet-based healthcare services of all stripes, we have to believe that Congress will enter the fray at some point, further reducing the conclusive value of any determination we might make here.

[12] Of course, "by its nature a declaratory judgment will almost always have some conclusive effect." Armstrong, 961 F.2d at 423. Our concern is that, by presenting a deliberately broad and contingent claim, plaintiffs seek to have the courts guide their business planning. That desire for comfort does not present a live controversy and is not a proper use of the limited resources of the federal courts. None of this should, of course, cast any doubt on the right of a plaintiff to seek a pre-enforcement declaratory judgment. Such a plaintiff must, however, show a likelihood of prosecution and a factual clarity beyond what we see here.

[sic] are likely to be affected by a declaratory judgment." Step-Saver, 912 F.2d at 649 n.9.

It is unclear on the basis of the pleadings before us that the plans of PSA or any of its partners are dependant on the result of this action. Plaintiffs "propose" to conduct business "pursuant to the following model." Compl. ¶ 15. Plaintiffs do not allege that, if we fail to grant the relief they seek, they will abandon their quest to set up an Internet pharmacy. Indeed, if, as they believe, their model is "compliant with a lawful construction of federal law," Compl. ¶ 16, there is no reason for them to change their plans based on the outcome here.

Instead, it appears that despite their confident claims, plaintiffs harbor doubts about the legality of their enterprise and seek to assuage their fears through this action. Entrepreneurship, however, brings with it certain risks. We do not believe it is the role of the federal justice system to preemptively resolve those risks so that plaintiffs can cash in without fear. Also, if, as plaintiffs contend, the DOJ is prosecuting others for the same conduct, Pl. Br. at 7, the scope of the DEA's power to regulate Internet pharmacies should soon be clear enough.[13] Thus, whether or not we reach the merits of this

[13] While, of course, those cases would not be res judicata as to the plaintiffs here, they should provide important clarifications of the DEA's enforcement plans and the legality of plaintiffs' proposed conduct. One presumes that other similarly situated plaintiffs will, if prosecuted, raise the sorts of claims plaintiffs seek to make here.

case, the legal issues that plaintiffs ask us to decide will be decided in short order.[14]

For all the reasons discussed above, we find that plaintiffs' claim is not ripe for adjudication.

C. Section 877

Defendants' third contention is that 21 U.S.C. § 877 vests exclusive jurisdiction to decide plaintiffs' claim in the courts of appeals. That Section vests authority to review agency "final determinations, findings, and conclusions" related to the Controlled Substances Act solely in appellate courts.[15] Were plaintiffs here challenging only the interpretive rule cited above, 66 Fed. Reg. 21181, the Government's argument might be convincing.[16] It is clear, however, that plaintiffs' challenge

---

[14] Such decisions might also help resolve some of the ripeness problems of plaintiffs' claim. If, for example, the DOJ begins prosecuting people who engage in conduct similar to conduct PSA partners have actually engaged in, that would resolve much of the contingent nature of this case.

[15] 21 U.S.C. § 877 reads, in its entirety: "All final determinations, findings, and conclusions of the Attorney General under [the CSA] shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive."

[16] We say "might" because it is not obvious that an interpretive rule such as this is the sort of determination at which Section 877 is directed. Section 877 seems to be directed to quasi-judicial determinations the agency makes regarding the rights of particular parties. Because PSA was not a party to the (continued...)

is not limited to a single interpretive rule, but instead seeks a clarification of its rights and duties under the Controlled Substances Act as a whole. Section 877 is not so broad as to deprive us of jurisdiction over such a general question.

Though we find that we lack jurisdiction at this time because plaintiffs do not have standing and because their claim is not ripe, in a different factual circumstance such that the constitutional requirements were met, we would have jurisdiction to decide the question plaintiffs pose.

Conclusion

We find that plaintiffs have failed to demonstrate that we have jurisdiction over the subject matter of this action. In particular, plaintiffs have not carried their burden to show that this matter constitutes a "case or controversy" within the meaning of Article III of the Constitution because they have not shown that they have standing or that their claim is ripe for adjudication. We will, therefore, dismiss plaintiffs' complaint. Because we do not reach the merits of plaintiffs' claims, this dismissal will be without prejudice to their reassertion in the future should the record become concrete enough to supply the requisite standing and ripeness.

---

[16](...continued)
DEA's interpretation in 2001 (and indeed may well not have existed in 2001), we would not accept, without some strong supporting evidence, that Congress intended for it to be entirely powerless to challenge the ruling in any forum outside of Section 877's thirty-day time limit.

BY THE COURT:

/s/ Stewart Dalzell, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PSA, LLC, et al.	:	CIVIL ACTION
v.	:	
ALBERTO R. GONZALES, et al.	:	NO. 06-3212

ORDER

AND NOW, this 13th day of November, 2006, upon consideration of defendants' motion to dismiss (docket entry # 4), plaintiffs' response (docket entry # 5), and defendants' motion for leave to file a reply (docket entry # 7) and for the reasons articulated in the accompanying Memorandum of Law, it is hereby ORDERED that:

1. Plaintiffs' complaint is DISMISSED; and

2. The Clerk of Court shall CLOSE this matter statistically.

BY THE COURT:

/s/ Stewart Dalzell, J.